4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2021-F-0366]

General Mills, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by General Mills, Inc., proposing that the food additive regulations be amended to provide for the safe use of vitamin D_3 as a nutrient supplement in yogurt at a level higher than is currently permitted.

DATES: The food additive petition was filed on February 3, 2021.

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marissa Santos, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-8160.

SUPPLEMENTARY INFORMATION: Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 1A4827), submitted on behalf of General Mills, Inc. by Exponent, 1150 Connecticut Ave., NW, Suite 1100, Washington, DC 20036. The petition proposes to amend the food additive regulations in § 172.380 (21 CFR 172.380) *Vitamin D_3* to provide for the safe use

of vitamin D_3 as a nutrient supplement in yogurt at a level higher than what is currently permitted.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(k) because the substance is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist that would warrant at least an environmental assessment (see 21 CFR 25.21). If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: April 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-08235 Filed: 4/22/2021 8:45 am; Publication Date: 4/23/2021]